40. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Bam*HI site at approximately 8150 to the BglII site at approximately 8750.

41. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Kpn*I site at approximately 6100 to the *Bgl*II site at approximately 6500.

42. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Kpn*I site at approximately 6100 to the *Bgl*II site at approximately 8750.

43. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Kpn*I site at approximately 6100 to the *Bgl*II site at approximately 9150.

E2 cont.

44. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Kpn*I site at approximately 3500 to the *Kpn*I site at approximately 6100.

45. A purified LAV λJ19 DNA fragment consisting of a restriction fragment generated by the *Kpn*I site at approximately 3900 to the *Kpn*I site at approximately 6100.--

REMARKS

Upon entry of this amendment, claims 28-29 and 32-45 will be pending in the instant application. Support for the amendments is found throughout the specification, for example, at page 3, line 27 through page 4, line 28, original claim 10, and page 13, line 19 through page 14, line 8. Accordingly, this amendment adds no new matter and entry is respectfully requested.

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The specification is objected to and claims 23-31 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is allegedly not commensurate with the scope of the claims. Applicants respectfully traverse the rejection.

It is alleged that the specification does not provide guidance as to the nucleotide sequence encompassed by the claimed invention. The Examiner states that one having skill in the art identifying HIV molecular clones from a different source would not know if he were in possession of the claimed invention. Thus, this rejection is based upon the scope of the HIV-1 DNA source being used here.

Applicants have canceled the claims and added new claims. The newly added claims 32-38 recite that the purified DNA fragments have the particular restriction sites encompassed by the claims. For example, newly added claim 32 recites a "purified DNA fragment having a *Bam*HI site at approximately 8150 and a *Bgl*II site at approximately 9150, wherein the DNA fragment consists of a restriction fragment generated by the *Bam*HI site at approximately 8150 to the *Bgl*II site at approximately 9150." Of course, one having ordinary skill in the art would be capable of determining whether or not the HIV-1 source has the restriction sites as described in the claims. Thus, the ordinary artisan would be capable of readily ascertaining whether or not he was in possession of the claimed invention.

Indeed, only permissible routine experimentation for determining whether or not a particular DNA source derived from HIV-1 is required to practice the claimed invention. This is not undue experimentation. For example, in Ex parte Mark, 12 U.S.P.Q.2d 1904, 1907 (Bd. Pat.

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App. & Int. 1989), the Board overturned a non-enablement rejection based on undue experimentation that was allegedly required to determine which Cys-containing proteins contain non-essential Cys residues by a method of deleting or replacing the Cys residues with another amino acid and then testing for ensuing biological activity. Similarly, all that is required here is the determination of whether or not the DNA source of HIV-1 contains the restriction fragments of the claimed invention.

With regard to the references cited to allegedly teach the genomic heterogeneity between HIV-1 quasispecies and variants, applicants respectfully submit that these references were all published after applicants' effective filing date. As stated in the Response to Paper No. 7 filed November 4, 1996, enablement is to be determined as of the filing date. In re Koller, 204 U.S.P.Q. 702, 706 (C.C.P.A. 1980); In re Hogan, 194 U.S.P.Q. 527, 537 (C.C.P.A. 1977). Indeed, later discovery of unknown variations does not render the original claims non-enabled. Hogan, 194 U.S.P.Q. at 537. Otherwise, "the opportunity for obtaining a basic patent upon early disclosure of a pioneer invention would be abolished." Hogan, 194 U.S.P.Q. at 537.

Holland *et al.* and Goodenow *et al.* were published in 1992 and 1989, respectively, long after even the last parent CIP of this case was filed. Thus, as in Hogan, applicants' original claim covered all known variations of the pioneering claimed subject matter. These variations were enabled by the specification as of the filing date. Other variations of the HIV-1 isolates were discovered after applicants' invention. Therefore, the Examiner cannot reject the claims under 35

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U.S.C. § 112, first paragraph, as allegedly being too broad, since Holland *et al.* and Goodenow *et al.* were not applicable as of the time of filing of even the last parent CIP of this case.

Furthermore, the specification utilizes LAV, a standard experimental strain and model for HIV-1 isolates at the time the claimed invention was made. As in the case of standard experimental models, at the time of this application, one skilled in the art would have expected the results obtained from LAV to be generalizable across other HIV-1 strains.

Indeed, the specification supports this position, for example, at page 7, where applicants teach using pLAV 13, a cDNA clone of LAV, in hybridization assays with LAV RNA from different sources. Therein applicants teach that LAV RNA was detected using the pLAV 13 as a probe when contacted with LAV from different sources, such as normal T cells, B-cell LAV-producing lines, CEM cells, and LAV from the bone marrow culture from a hemophiliac with AIDS. Thus, it is apparent that at the time the claimed invention was made, the inventors believed that the claimed invention was useful for any HIV-1 isolates.

In view of the foregoing remarks and amendments, applicants respectfully request withdrawal of the rejection.

Claims 23-31 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicants regard as the invention.

The Examiner states that the recitation of "at approximately" precludes identification of the precise location of the restriction sites. Applicants respectfully traverse the rejection.

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Contrary to the rejection, "precise location" of the claimed restriction sites is not required. Applicants may allow for some experimental error by using such words as "substantially" or "approximately" without rendering the claim indefinite. In re Morosi, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983). Indeed, this experimental error is clearly ascertained from applicants' specification, wherein the coordinates of the successive sites of the whole LAV genomes were estimated to be within ±200 base pairs. Therefore, applicants respectfully submit that there is no better way of claiming the fragments of the claimed invention. "While it is true that the word is not perfectly precise, under the circumstances of the present case there appears to be no other way for appellant to describe his discovery." In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). In view of the foregoing remarks, applicants respectfully request withdrawal of the instant rejection.

Applicants submit that the foregoing remarks and amendments should overcome all outstanding rejections and place this application in condition for allowance. At the very least, applicants respectfully request an indication of allowability for claims 39-45, which recite purified LAV λJ19 DNA fragments. In any event, the Examiner is invited to call the undersigned to discuss any remaining issues in this application in order to expedite the prosecution of this application.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner. Applicants submit that the proposed amendments do not raise new issues or

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necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Moreover, Applicants submit that the entry of the Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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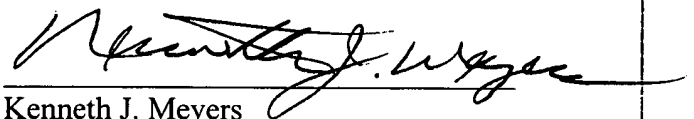
By: 
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